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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,125	01/12/2004	Dennis R. Burton	48503-00004	3579

23767 7590 09/15/2006

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EXAMINER

CHEN, STACY BROWN

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No. 10/756,125	Applicant(s) BURTON ET AL.	
	Examiner Stacy B. Chen	Art Unit 1648	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 14 August 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): See attached.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: 1-3,9,15-17,19-22,28,29,34-36,38-41,47,53-55,57-60,66,72-74,76,85 and 95.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 10,48,67,77-79,86 and 91-93.  
Claim(s) withdrawn from consideration: 11-14,30-33,49-52,68-71,87-90.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

***Advisory Action***

In the after-final amendment filed August 14, 2006, Applicant asserts that the Office action of June 13, 2006 should have been made non-final, as none of the amendments of the March 31, 2006 necessitated the new grounds of rejection set forth in the Office action. In response, the Office has considered Applicant's assertions and presents the following reasons for the finality of the Office action of June 13, 2006:

- With regard to the rejection of claims 77-79 and 91-93 under 35 U.S.C. 112, second paragraph, this rejection was set forth in the June 13, 2006 Office action. Applicant's amendment filed March 31, 2006, amended the claims to recite a new limitation, "An isolated population of monoclonal antibodies". This limitation altered the scope of the claim, thus necessitating the indefiniteness rejection.
- With regard to the rejection of claims 10, 48, 67 and 86 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, this rejection was set forth in the June 13, 2006 Office action. Applicant's amendment filed March 31, 2006, amended the claims to recite a new limitation, "comprising a therapeutically and prophylactically effective amount", whereas prior to the amendment, the claims recite, "comprising an effective amount". The terms "therapeutically" and "prophylactically" altered the scope of the claims, including the scope of the compounds listed in the claims, thus necessitating the written description rejection.
- With regard to the rejection of claims 76-79, 85-86, 91-93 and 95 under 35 U.S.C. 102(b) as anticipated by Valdés *et al.* (*Clinical and Diagnostic Laboratory immunology*, 2000, 7(5):856-857, "Valdés"), this rejection was set forth in the June 13, 2006 Office action.

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Applicant asserts that the amendment of March 31, 2006 to claim 76 merely incorporated the recitation of claim 75, now cancelled. The Office notes that claim 75 was never under examination because it was cancelled prior to the first Office action. As early as July 11, 2005, claim 75 was cancelled, which was prior to the December 6, 2005 first Office action on the merits. Therefore, the incorporation of limitations from claim 75 into claim 76 necessitates the prior art rejection.

Therefore, in view of the above analysis of the reasons for the finality of the Office action of June 13, 2006, finality is maintained. The merits of the after-final amendment filed August 14, 2006 are addressed below.

*Applicant's arguments regarding the rejection of claims 76-79, 85, 86, 91-93 and 95 under 35 U.S.C. 102(b) as anticipated by Valdés et al. (Clinical and Diagnostic Laboratory immunology, 2000, 7(5):856-857, "Valdés"), have been carefully considered.* The rejection is withdrawn with respect to claims 76-79, 85, 86 and 95, because Valdés does not disclose monoclonal antibodies. The rejection is withdrawn with respect to claims 91-93 because Valdés does not disclose the exact method by which the patient serum was collected (by syringe, or finger prick, etc.)

*Applicant's arguments regarding the rejection of claims 10, 48, 67 and 86 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement, have been carefully considered but fail to persuade.* Applicant argues that all of the varieties of molecules listed in the rejected claims are well known to those of skill in the art. Applicant

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points to paragraphs [0107-0108] as examples of molecules to be used. Applicant argues that there is sufficient structure/function description of this genus of molecules that one of skill in the art could conclude that the inventors had possession of the invention.

In response to Applicant's arguments, Applicant has failed to specifically address the merits of the rejection. In particular, Applicant has not explained how the specification adequately describes labels that are therapeutically or prophylactically effective to treat some unnamed disease or condition. One of skill in the art is not in possession of a label or reporter that treats or prevents any disease or condition. The specification does not adequately describe this embodiment. In another embodiment, claim 10 includes an immunoglobulin that treats or prevents another unnamed disease or condition. In order for the claims to be adequately described, the claimed elements must not only have a structure, but also a function and a correlation between the structure and function. Applicant has not demonstrated this because the claims generically treat or prevent something that is unnamed.

***In view of the Applicant's remarks, the rejection of claims 77-79 and 91-93 under 35 U.S.C. 112, second paragraph, is withdrawn.*** Given the understanding that, according to Applicant, a single epitope may comprise the entire sequence of a Dengue virus NS protein, the following enablement rejection is set forth.

(New Rejection) Claims 77-79 and 91-93 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies that bind at least one epitope comprising at least 103 amino acids, does not reasonably provide enablement for antibodies that bind at least one epitope that spans the entire amino acid sequence of the Dengue


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virus NS protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The specification fails to enable an isolated population of monoclonal mammalian anti-Dengue virus antibodies that specifically bind a single epitope that spans the entire length of the amino acid sequence of a Dengue virus NS protein. One of skill in the art would not expect that an antibody exists that has paratopes large enough to bind, at once, the entire amino acid sequence of an NS protein. Lacking evidence to support such an antibody, the claims are rejected for lack of enablement for the full scope of the claims.

### *Conclusion*

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

 9/14/06  
STACY B. CHEN  
PRIMARY EXAMINER